



CORDEN PHARMA COLORADO, INC.

ENVIRONMENTAL PROGRAMS STATUS REPORT

May 31, 2016

Pollution Prevention Certifications and Memberships:



ISO 14001

Introduction

Status Report History and Purpose

The annual Environmental Programs Status Report (Status Report), which was first issued in 1998, is part of the voluntary pollution prevention program at Corden Pharma Colorado. The Status Report serves as an update to the City of Boulder and Boulder County on the current status and results of Corden Pharma Colorado's pollution prevention activities. The goal is to provide our stakeholders and the general public with an understanding of Corden Pharma Colorado's environmental footprint. The Status Report also demonstrates Corden Pharma Colorado's commitment to continuous improvement in our operations, both benefiting the patients who depend on the medicines Corden Pharma Colorado produces and also protecting the environment. As always, a copy of the latest Environmental Programs Status Report is available for general public review on our website, www.cordenpharma.com/facilities/colorado.

Status Report Summary

In 2015, Corden Pharma Colorado decreased the production of bulk pharmaceuticals and pharmaceutical intermediates by 10 percent from 2014. Because of the different environmental impacts of each process, some environmental figures reflect negative trends, while others reflect improvement.

In 2014 and 2015, much focus was placed on optimization of solvent waste handling to minimize the impact of waste disposal. As a result, the percentage sent offsite for the beneficial purposes of recycling or energy recovery increased from 81 percent in 2013 to 99 percent in 2015. Another current area of focus is on implementing projects to substantially reduce the overall global energy impact of the Corden Pharma Colorado manufacturing processes, although the Corden Pharma Colorado Boulder facility does not always benefit from direct energy savings. These energy savings are realized by business partners and are not reflected in energy consumption figures in this report. Additional changes from 2014 to 2015 include a 55 percent reduction in total bulk liquid sent offsite, a 17 percent decrease in the amount of material recycled onsite per unit of production, a 3 percent decrease in water use, a 6 percent decrease in natural gas consumption, a 3 percent increase in electricity use, and an 8 percent increase in volatile organic compound emissions. Details can be found in the Summary Tables, beginning on page 13.

Status Report Outline

The remainder of this Status Report includes the following sections:

- **2015 Activity Background**
- **Environmental Compliance and Regulatory Status Changes**
- **Pollution Prevention Goals and Objectives**
- **2015 Summary Tables**

2015 Activity Background

This section of the Environmental Programs Status Report details the production and technical development activities at Corden Pharma Colorado and the voluntary environmental performance programs in which the company participates.

Production Activities Summary

Corden Pharma Colorado is a member of the Corden Pharma Group. The Corden Pharma Group includes a network of international companies that manufacture bulk intermediates, active ingredients, and final prescription and over-the-counter medicines.

The current focus of Corden Pharma Colorado's activities is the contract production of therapeutic peptides and highly active compounds along with complex small molecules. Corden Pharma Colorado sends the compounds it produces to other manufacturing sites for formulation into finished pharmaceutical products. As a multi-purpose facility that can handle small and large scale production, the medicinal compounds that Corden Pharma Colorado manufactures frequently change in response to market demand and the development of new therapeutic innovations.

The primary compounds that Corden Pharma Colorado produced in 2015 are active pharmaceutical ingredients or intermediates for the following medicines:

- Enfuvirtide (Fuzeon®)

Enfuvirtide was the first of a class of therapies called "fusion inhibitors" that block the AIDS virus from infecting healthy cells.

- Ganciclovir (Cytovene® or Cymevene®) and Valganciclovir (Cymeval® or Valcyte®)

Ganciclovir and Valganciclovir are drugs for the treatment of CMV retinitis in patients with compromised immune systems, including AIDS patients and organ transplant recipients.

- Saquinavir (Invirase®) and Nelfinavir (Viracept®)

Saquinavir and Nelfinavir are protease inhibitors that act to impede an enzyme that is vital in the later stages of HIV reproduction.

- Highly Active Pharmaceutical Products

Corden Pharma Colorado's facilities also include small scale manufacturing laboratories for the production of highly active compounds, drugs that are effective in very small doses. Some of the highly active compounds that Corden Pharma Colorado produced in 2015 are active ingredients for the endometriosis treatment, Nafarelin (Synarel®), and the osteoporosis treatment, Calcitriol (Rocaltrol®).

Technical Development Activities

Corden Pharma Colorado's technical development department designs manufacturing processes for intermediates and APIs that produce high purity medicinal compounds, while optimizing cost, reliability and safety. These same development activities also have environmental benefits:

- Improving the inherent safety of our manufacturing processes often entails the discovery and development of chemical synthesis routes that minimize or eliminate the use of environmentally undesirable materials.
- The improved synthesis routes that Corden Pharma Colorado scientists design also can help avoid high pressure and high temperature process conditions, with both safety benefits and energy savings.
- Starting with the simplest materials as building blocks for our products and improving the efficiency of our manufacturing processes minimizes the demand for raw materials.
- Maximizing the ability of our existing equipment to manufacture pharmaceutical products minimizes the need to construct and operate new facilities.

Corden Pharma Colorado's technical development facilities include both laboratories for process research and pilot scale production facilities for manufacturing drug compounds in the quantities necessary for approval by regulatory agencies, to supply the clinical trials for new drugs, and to demonstrate new manufacturing processes.

Voluntary Environmental Performance Programs

Corden Pharma Colorado participates in a variety of federal, state, local, and industry-wide initiatives that set challenging pollution prevention standards. The following are examples of the pollution prevention programs in which Corden Pharma Colorado currently participates:

City of Boulder Pollution Prevention Program

Corden Pharma Colorado has been a voluntary participant in the City of Boulder's Pollution Prevention Program since its inception. Participation in the Pollution Prevention Program began with the development of a "Pollution Prevention Master Plan and Statement of Commitments" and the setting of specific pollution reduction goals. Corden Pharma Colorado tracks the success of its environmental initiatives as a founding participant in the Pollution Prevention Program through this annual report to the City of Boulder, now titled "Environmental Programs Status Report."

Partners for A Clean Environment

Corden Pharma Colorado has been certified under Boulder County's Partners for A Clean Environment (PACE) program since 2001. PACE businesses must meet a stringent list of criteria, demonstrating a sincere commitment to a company-wide pollution prevention program and the implementation of projects that have a quantifiable benefit to the environment.

Colorado Environmental Leadership Recognition

The State of Colorado's Environmental Leadership certification recognizes companies that voluntarily perform above and beyond existing mandated environmental regulations. Environmental Leaders like Corden Pharma Colorado must have a comprehensive and operational environmental management system and a pollution prevention plan that commits the company to a program of continuous environmental improvement. In its letter announcing the Environmental Leadership certification, the Colorado Department of Public Health and Environment thanked Corden Pharma Colorado for the "effort and dedication" it brings to environmental issues. Under the Environmental Leadership program, Corden Pharma Colorado has participated in statewide pollution prevention workshops and mentoring programs. Since 2003, Corden Pharma Colorado has held the highest environmental honor that the State of Colorado bestows, the title of "Gold Level" Environmental Leader.

ISO 14001 Certification

Corden Pharma Colorado was certified under the ISO 14001 standard in 2006 and has maintained the certification since that time. Corden Pharma Colorado earned its ISO 14001 certification through a comprehensive independent audit of the company's environmental, health, safety, and security management system.

Colorado Environmental Partnership

The Colorado Environmental Partnership (CEP) is a membership organization consisting of representatives from the business community, government agencies, and public interest groups. The CEP hosts forums that provide opportunities for members and subject matter experts to discuss topics of mutual interest, share experiences, and recognize environmental achievements. The Colorado Environmental Partnership also collaborates with organizations that share its goals in hosting public events for business audiences on a range of topics related to environmental performance and sustainability. Corden Pharma Colorado has been an active member of CEP, encouraging employees to assume leadership roles and sponsoring some of the forums that the organization hosts.

Volunteer Work with Boulder County Parks and Open Space

Corden Pharma Colorado has been supporting Boulder County Open Space since 2009. Each year, Corden Pharma Colorado employee volunteers, along with their friends and families, have spent a day or two working to maintain and improve various open spaces. Employees have built fences, repaired trails, collected native seeds, fixed bridges, restored burned slash pile areas, removed infected trees, and worked on whatever else might be needed. In 2015 Corden helped with the construction of a wooden fence for a slash pile processing area on the Peak-to-Peak highway. In July 2016, Corden will support another activity, working on the Anne U. White trail.

Environmental Compliance or Regulatory Status Changes

Corden Pharma Colorado is subject to the Boiler MACT rule (40 CFR 63, Subpart DDDDD), which had a compliance date of January 31, 2016.

Pollution Prevention Goals and Objectives

Corden Pharma Colorado is committed to pursuing pollution prevention goals associated with our energy reduction, process waste minimization, and other pollution prevention efforts. This section details the progress Corden Pharma Colorado made in 2015 towards these three goal categories, including specific program achievements and plans for further action in 2016 and 2017.

Energy Reduction Goals

From 2010 to 2015, the company reduced electricity consumption by 20 percent and natural gas consumption by 2 percent. Overall, energy consumption at Corden Pharma Colorado decreased by 13 percent from 2010 to 2015 and by 25 percent since 2005 when the company's original energy goals were set.

Corden Pharma Colorado continues to identify, evaluate, and implement energy reduction measures. A number of initiatives have been completed over the last ten years that were highly effective. As explained below, two objectives (1f and 1g) substantially reduce the overall global energy impact of the Corden Pharma Colorado manufacturing processes, although Corden Pharma Colorado does not benefit from direct energy savings. These energy savings are realized by business partners and therefore are not reflected in energy consumption figures in this report. The following objectives are underway to continue to support energy reduction both on and off site:

Objective 1a: Implement a new standard for lighting in manufacturing buildings, where LED lights will be used in new installations. This will result in lower energy consumption.

Achievement: Corden Pharma Colorado has implemented the new lighting standard and has installed several dozen LED lights for specific applications to collect data on performance and functionality. Technology continues to evolve rapidly, especially for fixtures in electrically classified areas, and will continue to be evaluated and installed.

Objective 1b: Add direct power monitoring on all four main air compressors to better track performance, and implement any potential improvements identified.

Achievement: Corden Pharma Colorado installed the monitoring equipment to collect data for evaluation. This data monitoring prompted Corden Pharma Colorado to conduct a leak and usage study on the compressed air system. The study identified improvements to the system that were implemented and resulted in a measured reduction of compressed air usage that will save 156,000 KWH per year.

Objective 1c: Replace existing motors on the cooling tower system with more efficient motors.

Achievement: Corden Pharma Colorado replaced three 100 HP motors. The efficiencies improved from 88-92 percent efficient to NEMA nominal ratings of 95.4 percent efficient.

Objective 1d: Replace a fixed speed 40,000 CFM air handler unit in Plant 2 with an upgraded 50,000 CFM unit with variable frequency drive (VFD) control to allow ramping for optimum efficiency. This will not only optimize fan motor power but also the associated steam heating costs. Additionally, the new unit will support future expansion. The unit retains a swamp cooler system to provide optimum efficiency in cooling to the main manufacturing area.

Achievement: Completed in 2015.

Objective 1e: An additional air handling system is required to be installed for new product packaging rooms. As part of Corden Pharma Colorado's effort to minimize energy usage resulting from this, VFD's were installed on the supply air and air-conditioning portion of the new unit to optimize energy efficiency. Additionally, room functions including balancing and service function are all automated, allowing use of an idle mode that can reduce energy usage by over 40 percent while still meeting electrical classification requirements for the area when the room is not in active service.

Achievement: Completed in 2015.

Objective 1f: Improve the production efficiency of the existing pressure swing adsorption (PSA) nitrogen beds. These units supply nitrogen for manufacturing equipment, primarily for flammability control. If PSA nitrogen is not available, it is necessary to make-up the difference by vaporizing cryogenic nitrogen purchased from an outside supplier.

Achievement: Project completed in 2015. The initial 6 months of operation have shown a 40 percent increase in PSA production with no increase in power demand at the Corden Pharma Colorado facility. This results in less cryogenic nitrogen being purchased and therefore an overall lower global energy requirement for the nitrogen generation processes on-site, although direct energy savings are not located at the facility. Global energy savings shown reflects a 4th quarter 2015 commissioning of PSA improvements:

2015 Actual Savings	18,266 KWH
Original Goal Target Savings (annual)	270,000 KWH
2016 Projected Actual Savings	559,000 KWH

Objective 1g: A project in active commissioning is programming a control system to optimize nitrogen loading on the vent collection manifolds. This will reduce demand for

cryogenic nitrogen makeup into the PSA header while still maintaining stability of the vent collection system. Global energy savings projected:

Original Goal Target Savings (annual)	475,000 KWH
2016 Projected Actual Savings	1,500,000 KWH

This energy savings is not realized directly at the facility but impacts the overall global energy usage of the process. This will also eliminate ~174 tanker shipments annually of cryogenic nitrogen with additional energy savings and reduced industrial traffic as a result. These savings are independent of the PSA project identified above in Objective 1f.

Process Waste Minimization Goals

Corden Pharma Colorado strives to reduce the solvent waste and air emissions its pharmaceutical manufacturing processes generate. The company achieves these goals by modifying manufacturing processes to reduce the need for production material, recycling materials for re-use, controlling air emissions, and many other process waste minimization efforts. Over the years, Corden Pharma Colorado has successfully reduced the process waste from many manufacturing steps. The following specific objectives were designed to further advance these efforts in 2015 and 2016.

Objective 2a: Make additional emissions control investments in the North and South Pilot Plants. Specifically, pilot scale equipment will be connected to the emissions control system, providing the flexibility to deploy this equipment for commercial manufacturing purposes while maintaining low emissions levels.

Achievement: Starting in 2011 and continuing into 2015, Corden Pharma Colorado has connected additional pilot scale equipment in the North and South Pilot Plants to the emissions control system (ECS). These changes reduced VOC and HAP emissions from pilot scale manufacturing processes.

Objective 2b: Optimize waste tank utilization to minimize the amount of hazardous waste sent offsite for direct thermal destruction and maximize the amount sent offsite for use as an alternative fuel.

Achievement: Optimization measures have been implemented, and currently a large majority of this bulk waste is sent offsite for use as an alternative fuel. 43,500 gallons of waste was diverted to this purpose in 2013, and then approximately 180,000 gallons was diverted in 2014 and 170,000 gallons in 2015. Also as noted later in the report, the percentage of bulk waste sent offsite for energy recovery or recycling increased significantly from 53 percent in 2012 to 81 percent in 2013, and then to 99 percent in 2014 and 2015 due to implementation of this objective.

Objective 2c: Optimize aqueous waste workup onsite to minimize the amount of hazardous waste sent offsite for direct thermal destruction and maximize the amount treated in the onsite wastewater treatment plant or sent offsite for use as an alternative fuel.

Achievement: Implemented changes in 2014. As a result, in 2014, 32,000 gallons of aqueous waste that would have previously been shipped offsite for thermal destruction was instead treated in the onsite wastewater treatment plant, and this waste avoidance continued into 2015.

Other Pollution Prevention Goals

In addition to the energy efficiency and process waste minimization efforts listed above, Corden Pharma Colorado also set the following additional pollution prevention goal:

Objective 3a: Reduce paper usage by electronically managing some business records that the company currently prints on paper.

Achievement: Corden Pharma Colorado has previously converted several document types to electronic files. Corden Pharma Colorado is currently working on a multi-year implementation of an electronic data management system to convert additional records and forms to electronic storage.

Other Pollution Prevention Activities

The following activities represent additional efforts to prevent pollution in 2015 and 2016:

- Corden Pharma Colorado employees participated in the Boulder County Clean Air Consortium Summer Clean Air Challenge.

In addition to the projects and plans mentioned above, all Corden Pharma Colorado process teams continue to identify and evaluate pollution prevention opportunities in their areas of expertise. The Pollution Prevention Team supports and tracks all pollution prevention efforts at Corden Pharma Colorado, with a focus on reducing energy consumption and solvent usage and increasing solvent recovery in production processes.

2015 Summary Tables

2015 Production at Corden Pharma Colorado

In 2015, as measured by mass, Corden Pharma Colorado decreased the production of bulk pharmaceuticals and pharmaceutical intermediates by 10 percent from 2014. At the same time, the company's raw materials usage decreased by 42 percent due to a change in production mix and the amount of material required for each product. The environmental figures below reflect the result of both Corden Pharma Colorado's production changes as well as the company's implementation of pollution prevention measures.

Recycling of Raw Materials – Onsite Recycling

The list below compares process requirements and recycling volumes for chemicals that were recycled onsite. The "process requirement" represents the amount of each material needed during the year. The "amount recycled" reflects the reuse of a compound in a process, rather than disposing of it. The "percentage recycled" is the percentage of the process requirement that was met using recycled material instead of virgin material.

The overall amount of raw materials that Corden Pharma Colorado recycled onsite in 2015 decreased by 26 percent from 2014 and the amount recycled per unit of production decreased by 17 percent from 2014. These changes were due to changes in the production mix and the resulting changes in the company's demand for recyclable materials.

Chemical ¹	Process Requirement (lbs)	Amount Recycled (lbs)	Percentage Recycled
Acetonitrile	528,740	431,850	82%
Ethyl Acetate	696,199	175,521	25%
HMDS	95,508	47,245	49%
Methanol	1,123,795	82,011	7%
Toluene	189,223	24,456	13%
TOTAL		761,083	

¹ Offsite recycling is not included in this list. See table below, "Bulk Liquid Sent Offsite- Waste and Recycling"

Water Usage

The following table details water use at Corden Pharma Colorado in 2015.

Type of Usage	2011 (gallons)	2012 (gallons)	2013 (gallons)	2014 (gallons)	2015 (gallons)
Process	20,912,201	21,641,521	16,738,822	18,807,328	18,899,536
Commercial	1,747,121	1,655,609	1,609,853	1,637,228	1,747,121
Cooling	5,569,803	6,976,245	10,950,000	9,683,469	8,557,277
Irrigation	666,300	1,551,050	1,499,750	1,543,400	1,494,764
Total	28,895,425	31,824,425	30,798,425	31,671,425	30,698,698

Wastewater Pretreatment Plant Discharge

Corden Pharma Colorado sends aqueous wastes from production activities through its onsite pretreatment facility. Wastewater leaving the system is discharged to the City of Boulder treatment facility. The following table lists the major components of the wastewater that Corden Pharma Colorado discharges to the City of Boulder treatment facility:

	Discharge (in Pounds unless otherwise indicated)					
	1995 (Baseline)	2011	2012	2013	2014	2015
Volume, gal	21,035,000	7,228,695	8,581,463	10,107,002	9,865,603	8,890,417
Total Organic Content (TOC)	115,000	6,279	6,586	10,530	9,541	6,906
Chromium	31	8.2	5.1	2.9	3.8	1.6
Copper	4.3	16.8	14.5	31.1	16.4	12.2
Lead	2.8	0.0	2.2	2.9	4.1	3.7
Nickel	4.1	2.5	0.0	2.4	2.9	2.3
Zinc	73	54.2	35.2	40.3	72.1	43.2

Bulk Liquid Sent Offsite - Waste Disposal and Recycling

The following values represent the amount of material Corden Pharma Colorado sent offsite in bulk quantities for recycling, energy recovery, or incineration. Due to a change in production mix and the different solvents required for each product, from 2014 to 2015, the total bulk liquid sent offsite decreased by 55 percent, and bulk liquid sent offsite per unit of product produced decreased by 50 percent. However, the percentage sent offsite for the beneficial purposes of recycling or energy recovery remained at 99 percent. This improvement seen in 2014 and 2015 is a result of improved waste tank utilization, as explained above in Process Waste Minimization Goals.

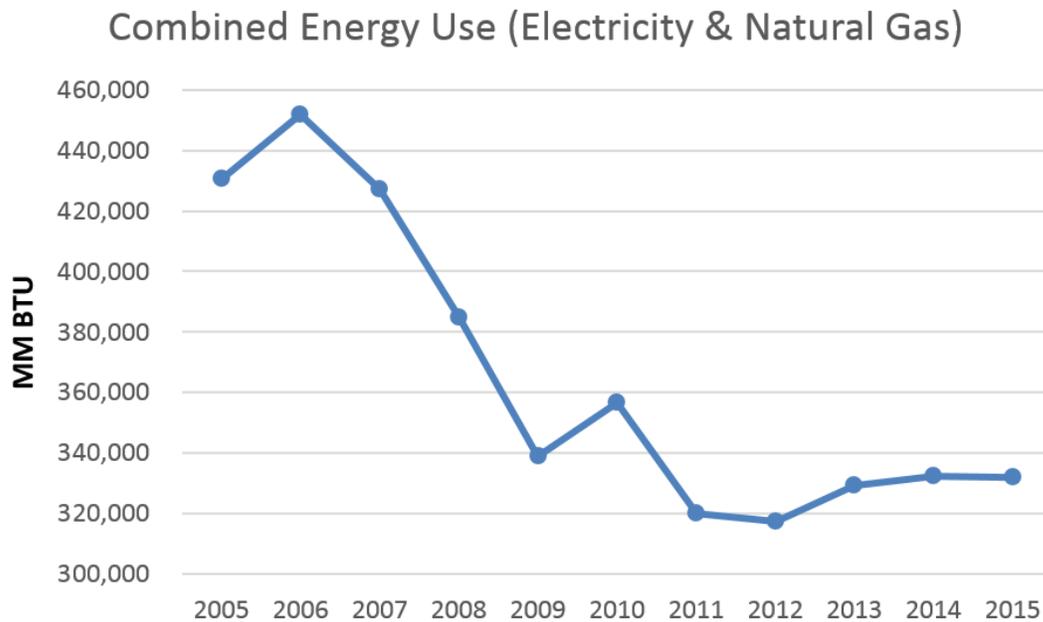
Description	2011	2012	2013	2014	2015
Total bulk liquid sent offsite (kg)	2,218,352	2,704,298	2,016,233	5,222,723	2,349,820
% Change from previous year	-57%	+22%	-25%	+159%	-55%
% Sent offsite for recycling	7%	2%	2%	53.7%	1%
% Sent offsite for energy recovery	49%	51%	79%	45.9%	98%

Energy Consumption

The following table presents natural gas and electricity consumption at Corden Pharma Colorado. From 2014 to 2015, electricity usage increased, while natural gas consumption decreased.

Energy Type	2011	2012	2013	2014	2015
Natural Gas (therms)	1,201,730	1,089,240	1,247,374	1,199,737	1,128,570
Electricity (KWH)	20,002,011	20,846,541	20,443,647	21,226,316	21,922,788

Energy reduction has been a priority at Corden Pharma Colorado for many years. A number of initiatives have been completed over the last ten years that were highly effective as shown in the following graph:



NOTE: Unit conversions made using Colorado Industrial Energy Challenge methodology, accounting for typical coal plant thermal efficiency.

Air Emissions

The following table displays Corden Pharma Colorado's air emissions, divided into Toxic Release Inventory (TRI) compounds, Hazardous Air Pollutants (HAPs), and Volatile Organic Compounds (VOCs). From 2014 to 2015, overall VOC emissions increased by 8 percent and HAP emissions stayed the same. Changes in the types of production activity caused the emissions to increase or decrease.

	1989 (Baseline)	2011	2012	2013	2014	2015
Reported under SARA Title III, Toxic Inventory Report (TRI) ⁴ [values in pounds]						
Acetone ³	242,500	250	250	1,100	490	1,400
Acetonitrile ^{1,2}	--	4,900	5,040	4,196	2,460	2,600
Cyclohexane ²	--	--	70	--	--	--
Dimethylformamide ^{1,2}	--	280	250	93	70	130
Hexane ^{1,2}	36,600	5,370	7,200	8,400	2,800	2,600
Hydrochloric acid ¹	4,000	300	110	40	420	160
Methanol ^{1,2}	109,600	4,300	4,600	4,780	6,100	9,100
Methyl chloride ^{1,2}	6,700	--	--	--	--	--
n-Methyl-2-pyrrolidinone ²	--	7	6	3	50	10
Methyl Tert-Butyl Ether ^{1,2}	--	4,150	2,690	3,820	4,310	4,230
Methylene chloride ¹	103,300	2,520	2,030	1,750	5,150	1,840
Pyridine ²	--	0	2	2	42	2
Toluene ^{1,2}	284,400	1,820	2,830	3,410	483	550
Triethylamine ^{1,2}	--	2	--	--	--	3
Total TRI air emissions (tons)	375	12	12	13	11	11
% change from previous year	--	-8%	0%	8%	-15%	0%
% change from 1989	--	-97%	-97%	-97%	-97%	-97%

Total HAP emissions (tons)	293	12	12	13	11	11
% change from previous year	--	-8%	0%	8%	-15%	0%
% change from 1989	--	-96%	-96%	-96%	-96%	-96%

Total VOC emissions (tons)	490	14	15	16	12	13
% change from previous year	--	-7%	7%	7%	-25%	8%
% change from 1989	--	-97%	-97%	-97%	-98%	-97%

¹ These chemicals are also classified as HAPs and are included in the HAP total above.

² These chemicals are also classified as VOCs and are included in the VOC total above.

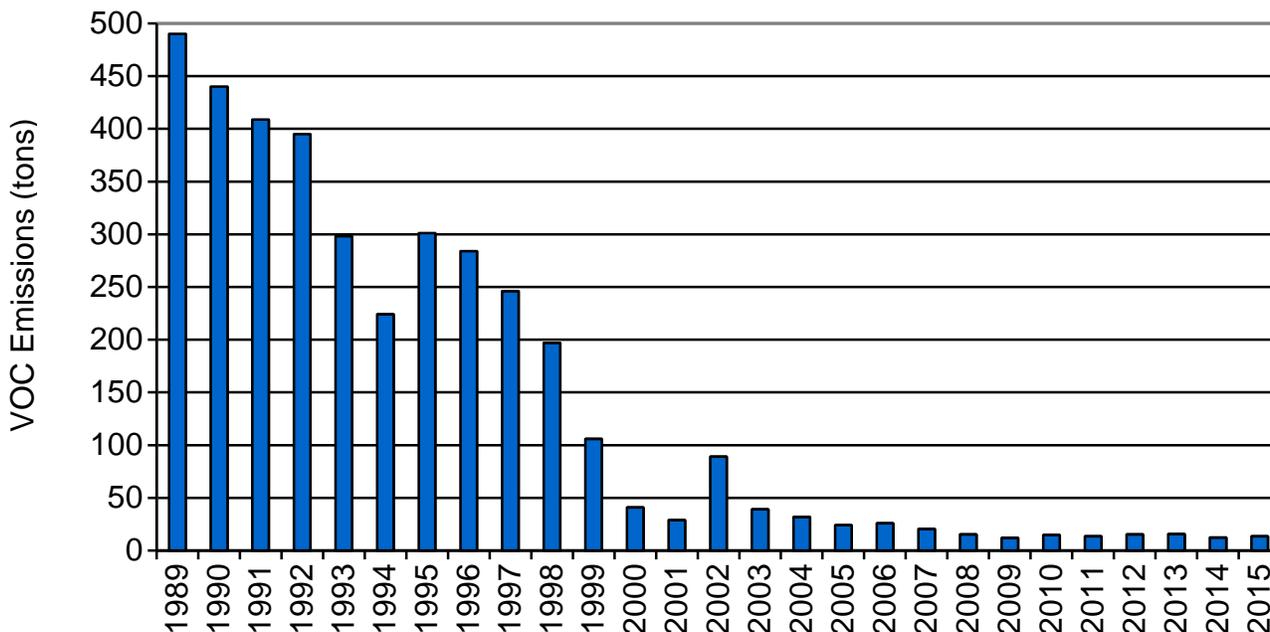
³ Acetone is no longer included in TRI. It is also no longer classified as a VOC. After 1996, it is not included in the VOC total.

⁴ Shaded blocks indicate that TRI reporting for that chemical was not required during that year. They are not included in the TRI emissions total.

HAP = Hazardous Air Pollutant

VOC = Volatile Organic Compound

Volatile Organic Compounds (VOC) Air Emissions Trend



General Waste Recycling

In 2015, Corden Pharma Colorado recycled a considerable amount of general waste. The totals presented here do not include recycling of removed manufacturing equipment. In 2015, Corden Pharma Colorado recycled over 84,000 pounds of office paper, shredded documentation, newspaper, cardboard, magazines, and phone books. These efforts helped Corden Pharma Colorado save an estimated 530 trees from destruction.

Type of Material	Pounds Recycled
Paper and Cardboard	84,000
Metals	1,000
Plastic	1,900
Compost	3,200